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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,510	03/24/2004	Tao Lu Lowe	059516-0058	3378

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,510	LOWE ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-24* is/are pending in the application.

4a) Of the above claim(s) *7 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,8,9 and 16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 1/16/09. Claims 1, 5 and 16 are amended. Claim 3 is canceled. Claims 1, 2 and 4-24 are pending. Claims 7 and 10-15 are withdrawn from consideration.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/16/09 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16, 17 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

4. The meets and bounds of biologically active or inert substance in claim 16 are not described.

Response to Arguments

5. Applicant's arguments filed 12/5/2008 have been fully considered but they are not persuasive.

6. Applicant says that the amendment to the claim 16 obviates the rejection. But the boundaries of "biologically active or inert substance" in claim 16 are not described and it is not known.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurisawa et al. ("Modulated degradation of dextran hydrogels grafted with poly(N-isopropylacrylamide-co-N,N-dimethylacrylamide) in response temperature," in Macromol. Chem. Phys. 199, 2613-2618 (1998).

9. Kurisawa described dextran hydrogen grafted with poly(N-isopropylacrylamide-co-N,N-dimethylacrylamide) (see the entire document with emphasis on the title, abstract, page 2614). The N,N-dimethylacrylamide is the hydrophobic segment, the dextran is the hydrophilic segment of claims 1 and 5, and the isopropylacrylamide is the smart segment of claim 1. The recitation in claim 2 that the hydrophobic or hydrophilic segment is hydrolytically or enzymatically degradable is an inherent characteristic of those segments. The hydrogel meets claim 6. Thus claims 1, 2, 5 and 6 are anticipated.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 4-6, 8, 9 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170) in view of Park et al. (US 6,271,278) or Hennink et al. (US 6,303,148).

13. Hennink (WO 98/00170) describes a hydrolysable hydrogels for controlled release of drugs such as protein drugs (abstract; page 1, lines 22-33; page 12, lines 14-31) with the hydrogel composition for the delivery of the protein drug meeting claims 16-19. The administration of the composition comprising the hydrolysable hydrogel polymer and the protein drugs to human (page 2, lines 4-19; page 3, line 30; page 5, lines 28 and 29; page 6, lines 7 and 8; and page 13, lines 9-19) meets the limitations of claims 20 and 21. The drugs in Henning are loaded into the hydrogel in an aqueous solution (page 4, lines 15-23; page 6, line 2) meeting

claim 23. The hydrolysable polymer of Hennink has polyglycolic acid and or polylactic acid spacers between mathacrylate type polymer and dextran (page 7, lines 24-36; pages 8; Examples 2, 3 and 4); the lactide or glycolide meets claim 4; the dextran meets claim 5 and the triblock polymer meets the generic polymer of claim 1 having the biodegradable segment, lactic acid and dextran and the smart segment, HEMA. Furthermore, the hydrogel composition is prepared in the form of microspheres (page 3, line 7; page 10, lines 26-34; page 12, line 7; page13, line 21) meeting claim 8. Claims 2 and 9 recite the properties of the polymer.

For claims 22 and 24, the artisan would have good reason to administer the composition having the appropriate concentration of the drug with the expectation that the delivery of the desired amounts of the drug would be released for effect the desired result. Hennink's (WO 98/00170) polymer does not have the smart polymer segment listed in the amended claim 1, that is polymers such as poly(N-isopropylacrylamide), poly(N-alkylacrylamide), poly(N-n-propylacrylamide), poly(N-isopropylmethacrylamide), poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) and elastin-like polypeptides.

But Park describes "smart" or "intelligent" hydrogels (column 33, line 14) formed from N-isopropylacrylamide olefinic monomers cross-linking particles of dis-integrants such as dextran sulfate (column 6, lines 7-10, 31, 35-42, 52, 56) for sustained/controlled delivery of drugs (column 30, line 10).

Also, Hennink (US 6,303,148) discloses polymers comprised of sensitive polymer such as poly-N-isopropylacrylamide grafted onto dextran for controlled release of drugs such as protein drugs (column 1, line 16; column 5, lines 35-44).

Therefore, taking the general teachings of the Hennink (WO 98/00170) in view of Park or Hennink (US 6,303,148), one having ordinary skill in the art would have reasonable expectation of success that using poly N-isopropylacrylamide in place of HEMA would produce a polymer that would be effective in sustained delivery of drugs such as protein drugs.

Response to Arguments

14. Applicant's arguments filed 12/05/08 have been fully considered but they are not persuasive as the arguments apply to the present rejections.

15. The arguments against Hennink as it regards the rejection under 35 USC 102 is moot in view of the new rejections under 35 USC 103.

16. Applicant argues that Hennink does not suggest the use of smart segments such as poly(N-isopropylacrylamide), poly(N-alkylacrylamide), poly(N-n-propylacrylamide), poly(N-isopropylmethacrylamide), poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) and elastin-like polypeptides and that Merchant does not cure the deficiency. The examiner agrees with the applicant that the Hennink does not use the specific smart segments in the polymer as now recited in amended claim 1. But, use of smart segments such as poly(N-isopropylacrylamide) have been known to be grafted to dextran or dextran derivative for use as sustained or controlled drug delivery (see Park and US 6,303,148 issued to Hennink as described above) so that the poly(N-isopropylacrylamide) smart or intelligent polymer can be used in place of the other smart polymer, HEMA of Hennink to achieve the anticipated delivery of protein drugs.

17. Claims 1, 2, 4-6, 8, 9 are 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bos et al., "Hydrogels for the Controlled Release of Pharmaceutical Proteins," in Pharmaceutical Technology, October, 2001, pp 110, 112, 114, 116, 118, 120.

18. Bos describes hydrogel for delivery of proteins listed under candidate proteins on page 110. The hydrogel is formulated form natural materials, synthetic polymers and responsive polymers (see list under hydrogel material on page 112) and listed under responsive polymers are methacrylates and poly(n-isopropylacrylamide). Claim 2 described the inherent characteristic/properties of the polymeric material of claim 1. The polymeric material of Boss microsphere (see pages 116, 118) meeting claim 8. The protein pharmaceutical meets claims 16-19. Boss contemplates administering the hydrogel composition so that claim 20 is met and because candidate protein such as erythropoietin, IL-2 and the rest of the candidate proteins are suitable for administration to human, claims 21 and 22 are also rendered obvious. The polymer and the candidate proteins are mixed to form the hydrogel composition (see the pages 110, 112, 114) meeting claims 23 and 24. Bos specifically mentions modified hydrogels comprised of dex-lactate-HEMA (page 114) and for hydrogel of that nature, dextran meets the hydrophilic segment of claims 1, 6; the lactate meets the hydrophobic segment of claims 1, 4; the HEMA meets the smart segment of claim 1, 9 except that the smart segment of claim 1 is poly(N-isopropylacrylamide), poly(N-alkylacrylamide), poly(N-n-propylacrylamide), poly(N-isopropylmethacrylamide), poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) or elastin-like polypeptides. But, in Boss poly(n-isopropylacrylamide) and methacrylates are listed as responsive polymers (page 112, under hydrogel materials and also under abbreviations) with HEMA being a methacrylate. Thus, taking the teaching of Boss, one having ordinary skill in the

art at the time the invention was made would have reasonable expectation that using poly(n-isopropylacrylamide) in place of the HEMA in the dex-lactate-HEMA would produce a hydrogel that would provide the desired controlled release of the protein pharmaceuticals.

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618